K043207

NOV 0 4 2005

GE Infrastructure
Water & Process Technologies

510(k) SUMMARY

DATE PREPARED: **November 2, 2005**

1. SUBMITTER

GE Infrastructure, Water & Process Technologies
5951 Clearwater Drive
Minnetonka, MN 55343-8995

2. CONTACT PERSON

Name: Charlene Nash
Phone: (952) 988-6359
Fax: (952) 988-6136
Email: Charlene.nash@ge.com

3. DEVICE IDENTIFICATION

Common Name: Ozone Generator/Ozone Generating System

Trade Name/Proprietary Name: O_3Z Ozone System used on the Solution Delivery Systems (SDS) manufactured by GE Infrastructure, Water & Process Technologies

4. CLASSIFICATION NAME AND REFERENCE

Classification Names: Tank, Holding, Dialysis and Accessories

Classification: Class II, 21 CFR 876.5820
Panel: Gastroenterology
Product Code: FIN

5. PREMARKET NOTIFICATION NUMBER: K043207

General Electric Company
5951 Clearwater Drive
Minnetonka, MN 55343-8995
USA

T 952-933-2277
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6. **INDICATION FOR USE:** The O_3Z Ozone System is an optional accessory for the Solution Delivery Systems (SDS) manufactured by GE Infrastructure, Water & Process Technologies, and is intended to be used for disinfection of the SDS bicarb mixing and distribution system. The mix tank of the SDS system is filled with either RO or deionized water and the mix tank ozone concentration is increased to 0.70 mg/L. The solution is then distributed to the distribution tank of the SDS system. From the distribution tank, the ozonated water is distributed throughout the distribution loop of the SDS system until a minimum ozone concentration level of 0.30 mg/L is established at the end of the SDS bicarb distribution loop. The solution is then recirculated for a minimum of 15 minutes throughout the distribution system. To complete the disinfection process, the system is then rinsed with RO or deionized water until the system is residual free of ozone.

7. **DEVICE DESCRIPTION:** The Ozone Generating System attaches to the Solution Delivery System (SDS) through a valve bypass system and an injector. It is wall mounted in the vicinity of the SDS and is connected to the injector, which is installed in the output piping of the mix pump. The SDS mix tank is filled with RO or DI water; the bypass valves are manually configured for ozone production and then the mix pump is started, causing the injector to draw O_3/air mixture into solution. When the proper concentrations of ozone are achieved, the ozonated water is re-circulated throughout the mixing and delivery system to disinfect the fluid path.

8. **STATEMENT OF SUBSTANTIAL EQUIVALENCE:** The ozone generator for system disinfection is substantially equivalent in technological characteristics of the Karlson Ozone Sterilizer (K873200). It is substantially equivalent in intended use to Minncare®, which is commonly used in hemodialysis clinics to disinfect the reverse osmosis water purification equipment and the water distribution loop and Renalin® (K830575), another common disinfectant used in dialysis clinics primarily to reprocess dialyzers and disinfect dialysis machines.

9. **PERFORMANCE: SAFETY AND EFFECTIVENESS INFORMATION**
Testing of the ozone generator demonstrated that the disinfection process was effective, reliable and consistent in reducing microorganisms with high total organism counts to acceptable levels after disinfection when used in accordance with the Operation and Maintenance Manual for the Ozone Generating System.

General Electric Company
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 4 2005

Ms. Charlene Nash
Quality Assurance & Regulatory Affairs Manager
GE Infrastructure Water & Process Technologies
GE Osmonics, Minnetonka Medical Operations
5951 Clearwater Drive
Minnetonka, Minnesota 55343

Re: K043207
Trade/Device Name: 0_3Z 0Zone System
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: NII
Dated: October 14, 2005
Received: October 19, 2005

Dear Ms. Nash:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

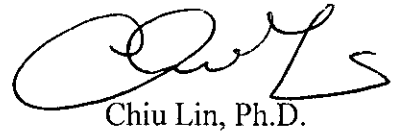
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GE Infrastructure, Water & Process Technologies
5951 Clearwater Drive
Minnetonka, MN 55343-8995

510(k) Number (if known): K043207

Device Name: O_3Z Ozone System used on the Solution Delivery Systems (SDS) manufactured by GE Infrastructure, Water & Process Technologies

Indications for Use Statement

The O_3Z Ozone System is an optional accessory for the Solution Delivery Systems (SDS) manufactured by GE Infrastructure, Water & Process Technologies, and is intended to be used for disinfection of the SDS bicarb mixing and distribution system. The mix tank of the SDS system is filled with either RO or deionized water and the mix tank ozone concentration is increased to 0.70 mg/L. The solution is then distributed to the distribution tank of the SDS system. From the distribution tank, the ozonated water is distributed throughout the distribution loop of the SDS system until a minimum ozone concentration level of 0.30 mg/L is established at the end of the SDS bicarb distribution loop. The solution is then recirculated for a minimum of 15 minutes throughout the distribution system. To complete the disinfection process, the system is then rinsed with RO or deionized water until the system is residual free of ozone.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use _X_
(Per 21 CFR 801.109)

Sheila A Murphy MD 11/3/05
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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